

## REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on April 25, 2003, the Examiner objected to claim 10, rejected claims 1-28 under 35 U.S.C. §112, second paragraph, rejected claims 1, 3, 4, 7, 10, 12-14 and 17 under 35 U.S.C. §103(a) as being unpatentable over Hansjurgens (U.S. Patent No. 3,774,620, hereinafter "Hansjurgens"), rejected claims 1-5, 7, 8, 10-15, and 17-18 under 35 U.S.C. §103(a) as being unpatentable over Nemec (U.S. Patent No. 4,153,061, hereinafter "Nemec"), rejected claims 6, 9, 16 and 19 under 35 U.S.C. §103(a) as being unpatentable over Nemec in view of Madsen Jr. et al (U.S. Patent No. 5,776,173, hereinafter "Madsen"), and rejected claims 20-28 under 35 U.S.C. §103(a) as being unpatentable over Nemec in view of Madsen. Accordingly, Applicants respectfully provide the following:

### Objection to Claim 10

Applicants respectfully submit that the amendments provided herein overcome the objection made by the Examiner to claim 10.

### Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, the Examiner rejected claims 1-28 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully submit that the amendments provided herein overcome the rejection made by the Examiner to claims 1-28 under 35 U.S.C. §112, second paragraph.

### Rejection under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1, 3, 4, 7, 10, 12-14 and 17 under 35 U.S.C. §103(a) as being unpatentable over Hansjurgens, rejected claims 1-5, 7, 8, 10-15, and 17-

18 under 35 U.S.C. §103(a) as being unpatentable over Nemec, rejected claims 6, 9, 16 and 19 under 35 U.S.C. §103(a) as being unpatentable over Nemac in view of Madsen, and rejected claims 20-28 under 35 U.S.C. §103(a) as being unpatentable over Nemac in view of Madsen. Applicants respectfully submit that the claim set as provided herein is not made obvious by the cited references.

Hansjurgens teaches an electromedical instrument for interference current therapy with at least two circuits acting by way of electrodes on the object of the treatment, by means of which circuits an interference effective for stimulation purposes is produced at a target position on the object by superimposition of two or more currents which are in themselves ineffective alone for stimulation purposes and which differ from one another by a low-frequency value. (col. 1, lines 4-12)

Nemec teaches a system having three separate pairs of electrodes each of which is responsible for passing electrical current through the body region being treated. In accordance with the present invention two of a given alternating currents have frequencies which differ from between 0 Hz to 100 Hz so as to produce a beat frequency ideally suited for electrode treatment. The third electrical current has a frequency which varies either from that of one of the first two frequencies or from their beat frequency as arithmetic mean by a difference equal to at most 1 Hz. Thus there is produced a heterodyned and modulated overall signal which is extremely effective for internal body treatment. At the same time the use of six different electrodes at six separate and spaced-apart locations allows the thus ideally balanced current to be applied for the production of stereometric endogenous stimulation having slowly varying intensity. (col. 2, lines 13-30)

Madsen teaches an interferential electro-stimulation device and, more particularly to a novel, portable, microprocessor-based, digitally-controlled electro-stimulator capable of multi-mode operation for the delivery of electric current therapy to a patient. The instant stimulator supports either bipolar or quadrapolar operation utilizing, respectively, one or two pairs of electrodes attached to a patient's body proximate the area requiring therapy. A wide range of treatment modalities are easily selected by means of the digital controls and the LCD display. Usage information is stored in internal, non-volatile memory for later readout by the prescribing practitioner. (col. 4, lines 16-27)

In contrast, independent claims 1, 10 and 20 of the present invention as provided herein, claim limitations relating to a first electrical circuit having a first current source, a first variable base frequency, a first beat frequency, and a first pair of treatment electrodes, wherein the first pair of treatment electrodes are configured for selective coupling to opposing sides of a patient's body with respect to a spinal column of the patient to allow the first electrical circuit to interact with and stimulate a nerve span of the patient's spinal column; a second electrical circuit having a second current source, a second variable base frequency, a second beat frequency, and a second pair of treatment electrodes, wherein the second pair of treatment electrodes are configured for selective coupling to opposing sides of the patient's body with respect to the spinal column of the patient to allow the second electrical circuit to interact with and stimulate the nerve span of the patient's spinal column; a third electrical circuit having a third current source, a third variable base frequency, a third beat frequency, and a third pair of treatment electrodes, wherein the third pair of treatment electrodes are configured for selective coupling to opposing sides of the patient's body with respect to the spinal column of the patient to allow the third electrical circuit to interact with and stimulate the nerve span of the patient's spinal column; and a fourth

electrical circuit having a fourth current source, a fourth variable base frequency, a fourth beat frequency, and a fourth pair of treatment electrodes, wherein the fourth pair of treatment electrodes are configured for selective coupling to opposing sides of the patient's body with respect to the spinal column of the patient to allow the fourth electrical circuit to interact with and stimulate the nerve span of the patient's spinal column, and wherein current from the first, second, third and fourth electrical circuits selectively provides interferential treatment to the nerve span of the patient's spinal column. The references cited by the examiner do not teach or suggest these limitation. And, in light of the inclusion of the limitations, the standard for a Section 103 rejection is set for in M.P.E.P 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Applicants respectfully submit that the prior art references do not teach or suggest the limitations claimed. And, since the references cited by the Examiner do not teach or suggest each and every limitation of the independent claims, Applicant respectfully submits that the cited references do not make obvious the claim set.

Additionally, Applicants respectfully submit that Hansjurgens teaches away from the limitations claimed in the present invention. In particular, Hansjurgens' are "based on the knowledge that interference or equally strong interference does not obtain in the entire range of intersection, but that rather with constant electrical values of the instrument and a constant

arrangement of the electrodes for the interference region...” (col. 1, lines 64-68 to col. 2, lines 1-2)

In contrast, the independent claims of the present invention include limitations based on variable base frequencies. For at least this reason, Applicants respectfully submit that the claimed invention is not made obvious by the cited reference.

Further, Applicants respectfully submit that none of the references, alone or in combination, teach the interaction with and stimulation of a nerve span of the patient’s spinal column. For at least this reason, Applicants respectfully submit that the claimed invention is not made obvious by the references cited by the Examiner.

Thus, Applicants respectfully submits that none of the claims of the claim set provided herein is either anticipated or made obvious from the references cited by the Examiner.

CONCLUSION

Applicants submit that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,



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